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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,174	06/27/2001	William M. Blackshear JR.		5327

7590 10/20/2005

ARTHUR W. FISHER, III  
Suite 316  
5553 West Waters Avenue  
Tampa, FL 33634

EXAMINER

RINES, ROBERT D

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/894,174		BLACKSHEAR ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Robert D. Rines		3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*LP*

**DETAILED ACTION**

*Notice to Applicant*

[1] This communication is in response to the patent application filed on 27 June 2001.

Claims 1-14 are pending.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[2] Claims 5-10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[A] In claim 5 of the present case, the applicant recites the phrase "assessing by surgical vascular to determine" (Claim 5; lines 1-2). It is unclear as to what the applicant intends to convey with this statement. For example, does the applicant intend to indicate an exploratory surgical procedure, or a non-surgical assessment, or some other meaning? Therefore, claim 5 is rejected under 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

[B] Claims 6-10 and 13, by virtue of their dependence on claim 5, and when analyzed in the same manner described with respect to claim 5, also fail to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Therefore, claims 6-10 and 13 are rejected under 35 U.S.C. 112 as well.

[C] Claim 7 recites the limitation "the vascular surgery facility" in line 3 of claim 7. There is insufficient antecedent basis for this limitation in the claim.

[D] Claim 13 recites the limitation "the vascular surgery facility" in line 4 of claim 7. Further, the applicant recites the limitation "the healthcare facility" in line 6 of claim 7. There is insufficient antecedent basis for either of these limitations in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

[3] Claims 1-6, 8-13 is rejected under 35 U.S.C. 102(e) as being anticipated by Crutchfield et al. (United States Patent #6,699,193).

[A] As per claim 1, Crutchfield et al., discloses a method for the management of persons at risk of complications of arterial occlusive disease (Crutchfield et al.; Abstract) comprising; evaluating a population of persons to identify those persons potentially at risk of complications of arterial occlusive disease (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39), examining those persons evaluated potentially at risk of complications of arterial occlusive disease (Crutchfield et al.; col. 9, lines 30-39), classifying those persons determined to be at risk of complications of arterial occlusive disease (Crutchfield et al.; col. 9, lines 40-52 and col. 10, lines 6-20), treating those persons classified at risk of complications of arterial occlusive disease (Crutchfield et al.; col. 9, lines 53-67 and col. 10, lines 1-5) and monitoring those persons treated for arterial occlusive disease to determine prognosis and efficacy of treatment (Crutchfield et al.; col. 9, lines 40-45, col. 16, lines 54-64, col. 20, lines 21-40 and col. 44, lines 32-36).

[B] As per claim 2, Crutchfield et al., discloses those persons classified as potentially at risk of complications of arterial occlusive disease are referred for noninvasive vascular evaluation (Crutchfield et al.; col. 9, lines 14-20).

[C] As per claim 3, Crutchfield et al., discloses patient data sets are compared against the predetermined set of disease specific criteria (Crutchfield et al.; col. 9, lines 25-29 and lines 30-39) to provide a preliminary classification of those persons potentially at risk and those persons

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not at risk of developing complications of arterial occlusive disease (Crutchfield et al.; col. 9, lines 40-52).

[D] As per claim 4, Crutchfield et al., discloses the results of the individual noninvasive vascular evaluations are reviewed for final classification of the person or patient as at risk or not at risk (Crutchfield et al.; col. 9, lines 1-32).

[E] As per claim 5, Crutchfield et al., discloses assessing by vascular surgical to determine if revascularization is necessary (Crutchfield et al.; col. 19, lines 55-67) and to identify those persons or patients as clinical indication for operation or indication for no operation (Crutchfield et al.; col. 19, lines 55-67).

[F] As per claim 6, Crutchfield et al., discloses wherein persons or patients assessed as no indication for operation (Crutchfield et al.; col. 9, lines 30-35) are monitored with increased precautions for detection of any deterioration dictating reassessment (Crutchfield et al.; col. 19, lines 50-67).

[G] As per claim 8, Crutchfield et al., discloses the persons or patients assessed as clinical indication for operation are informed of the assessment (Crutchfield et al.; col. 19, lines 55-62), the person or patient electing either revascularization and periodic evaluation or routine wound care and periodic revaluation (Crutchfield et al.; col. 19, 55-62).

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[H] As per claim 9, Crutchfield et al., discloses that the persons or patients are monitored with increased precaution for detection of deterioration dictating reassessment (Crutchfield et al.; col. 19, lines 55-62).

[I] As per claim 10, Crutchfield et al., discloses the persons or patients are reassessed for revascularization when medically dictated (Crutchfield et al.; col. 19, lines 55-62).

[J] As per claim 11, Crutchfield et al., discloses wherein routine care and precautions is administered to not at risk persons or patients without limb ulcers (Crutchfield et al.; col. 19, lines 55-62).

[K] As per claim 12, Crutchfield et al., discloses that not at risk persons or patients with ulcers receive routine wound care and periodic reevaluations (Crutchfield et al.; col. 19, lines 55-62).

[L] As per claim 13, Crutchfield et al., discloses at risk persons or patients assessed as no indication for operation or operation not elected by patient and clinical indication for operation undergoing or not undergoing revascularization at the vascular surgery facility receive routine wound care and periodic reevaluations with increased precautions at the healthcare facility (Crutchfield et al.; col. 19, lines 55-62).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

[4] Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield et al. and Carman (American Family Physician 2000; 61: 1027-1032, 1034).

[A] As per claim 7, Although Crutchfield et al., discloses recommended interventional strategies or therapeutics (Crutchfield et al.; col. 19, lines 55-62) for cases in which arterial blood



occlusion is worsening in the patient based on periodic examinations. Crutchfield et al., fails to expressly disclose the development of ulcers, pair and/or gangrene as symptoms indicating required reassessment for interventional strategies.

[i] However, Carman does disclose when the patient develops ulcers, pair and/or gangrene, the person or patient is referred to the vascular surgery facility for reassessment for a no indication for operation and clinical indication for operation for reevaluation and appropriate medical procedure and regimen (Carman: Abstract).

[ii] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Crutchfield et al., with those of Carman. The motivation would have been to provide a system and method capable of monitoring the vascular health of an individual and determining appropriate interventional strategies based on non-invasive vascular assessment (Crutchfield et al.; col. 19, lines 55-62), as well as presentation of classical symptoms such as the development of ulceration or gangrene (Carman; Abstract). Further motivation would have been to enable the physician to consider the appropriate timing for referral to a vascular specialist when symptoms progress (Carman; Abstract).

[B] As per claim 14, Crutchfield et al., discloses a method for the management of persons at risk of complications of arterial occlusive disease including evaluating a population of persons to identify those persons potentially at risk of complications of arterial occlusive disease

(Crutchfield et al.; col. 9, lines 24-29 and lines 30-39) examining those persons evaluated potentially at risk of complications of arterial occlusive disease (Crutchfield et al.; col. 9, lines 30-39), classifying those persons determined to be at risk of complications of arterial occlusive disease (Crutchfield et al.; col. 9, lines 40-52 and col. 10, lines 6-20), treating those persons classified at risk of complications of arterial occlusive disease (Crutchfield et al.; col. 9, lines 53-67 and col. 10, lines 1-5) and monitoring those persons treated for arterial occlusive disease to determine prognosis and efficacy of treatment (Crutchfield et al.; col. 9, lines 40-45, col. 16, lines 54-64, col. 20, lines 21-40 and col. 44, lines 32-36).

[i] Crutchfield et al., further discloses a non-invasive method that may be used by a physician to detect any deviations from vascular health by evaluating specific parameters in a wide variety of situations including periodic physical examinations, battlefield situations, scenes of emergency, and in neurological clinics (Crutchfield et al.; col. 9, lines 15-30). The examiner is interpreting Crutchfield's listed uses to encompass the applicant's limitations of: a healthcare facility primarily responsible for the care of a population of persons who may include persons at risk of complications of arterial occlusive disease, a management center responsible for management and administration of said method including the preliminary and final classification, a noninvasive vascular facility performing noninvasive vascular evaluations the management center derive data upon which to determines final classification of not at risk or at risk.

[ii] Although Crutchfield et al., does disclose use of his method to enable a physician to determine and recommend treatment options (Crutchfield et al.; col. 19, lines 55-62) Crutchfield

does not specifically disclose surgical intervention or the involvement of a vascular surgical facility.

[iii] However, as is noted by Carman, standard medical treatment for arterial occlusive disease in which symptoms are severe or worsening includes vascular surgery/revascularization upon referral to a vascular surgery facility assessing persons at risk of complications of arterial occlusive disease for vascular surgery (Carman; Abstract).

[iv] Regarding claim 14, the obviousness and motivation to combine as discussed with regard to claim 7 above are applicable to claim 14 and are herein incorporated by reference.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Meaney et al., METHOD AND APPARATUS FOR MAGNETIC RESONANCE ANGIOGRAPHY USING CONTRAST AGENTS, United States Patent #5,924,987; Kirshner, COMPUTERIZED INTERACTIVE METHOD AND SYSTEM FOR DETERMINING A RISK OF DEVELOPING A DISEASE AND THE CONSEQUENCES OF DEVELOPING THE DISEASE, United States Patent #6,322,504; Gray, DIAGNOSTIC ENHANCEMENT METHOD AND APPARATUS, United States Patent #6,149,585; Whitehouse, METHODS AND COMPOSITIONS FOR THE TREATMENT OF PERIPHERAL ARTERY DISEASE, United States Patent Application Publication #2002/0115603; Muhlestein et al., METHOD FOR

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EVALUATING AND APPLYING AND INDIVIDUAL'S GENETIC CHARACTERISTICS TO DETERMINE RESPONSE TO CARDIOVASCULAR MEDICATION THERAPY, United States Patent Application Publication #2002/0164598.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert D. Rines whose telephone number is 571-272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RDR

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10-14-2005

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SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3600